

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, ex rel.)	CASE NO. 5:15-cv-0611
KEVIN MANIERI,)	
)	
PLAINTIFF-RELATOR,)	JUDGE SARA LIOI
)	
vs.)	MEMORANDUM OPINION
)	
AVANIR PHARMACEUTICALS, INC.,)	
)	
DEFENDANT.)	

Before the Court is the motion of defendant Avanir Pharmaceuticals, Inc. (“Avanir”) to dismiss the second amended complaint. (Doc. No. 52 [“MTD”].) Plaintiff Kevin Manieri (“Manieri”) filed a memorandum in opposition. (Doc. No. 53 [“Opp’n”].) Avanir filed a reply. (Doc. No. 54 [“Reply”].) For the reasons set forth herein, the motion is granted.

I. Background¹

The following background information was set forth by the Court in its Memorandum Opinion and Order dated July 28, 2020 (*See* Doc. No. 50 [“MOO”]) and is repeated here, in substantial part, for context.

On March 27, 2015, Manieri filed a complaint, individually and on behalf of the United States of America,² alleging that defendant Avanir had violated the False Claims Act, 31 U.S.C. § 3729, *et seq.* (“FCA”), and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (“AKS”). (Doc.

¹ All page number references herein are to the page identification number generated by the Court’s electronic filing system.

² Manieri’s claims against Avanir that were brought on behalf of the United States of America (which had intervened on September 26, 2019 (*see* Doc. No. 25)), were resolved on October 24, 2019 by way of a settlement and joint stipulation of partial dismissal. (*See* Doc. No. 28.)

No. 1, Complaint, [“Compl.”] ¶ 1.) Manieri alleged that Avanir pays speaking fees to physicians around the country in exchange for their promise to prescribe a drug that Avanir sells as a treatment for a rare neurological condition. He alleged that this conduct led to the submission of false or fraudulent claims for prescriptions to Medicare patients written in 2013 and 2014. (*Id.* ¶¶ 2, 136–53.)

Manieri also alleged that he had been employed by Avanir from August to November 2014. (*Id.* ¶ 10.) He claimed his employment was terminated in retaliation for his objections to the illegal kickback scheme in conversations with Avanir’s Vice President of Sales, Michael McFadden (“McFadden”). (*Id.* ¶¶ 154–61.)

On December 17, 2019, Manieri filed his first amended complaint (Doc. No. 35, First Amended Complaint [“FAC”]), wherein he again alleged that Avanir terminated his employment in retaliation for his objection to certain physicians’ “participation in the speaker program as a means to unlawfully induce prescriptions of [the drug].” (*Id.* ¶ 6.) Despite that allegation in the introduction to the FAC, when Manieri described in detail the circumstances surrounding the termination of his employment, he alleged (exactly as he had in his initial complaint) that, during a meeting in Boston on November 17, 2014, another regional business manager (“RBM”) complained to Manieri that some of the RBM’s direct reports were not performing well. Manieri suggested that the RBM consider terminating the underperforming employees. (*Id.* ¶¶ 147–48; Compl. ¶¶ 131–32.) Another sales representative overheard Manieri’s comment and disagreed; that representative subsequently passed on a complaint to McFadden. (FAC ¶ 149; Compl. ¶ 132.) A few days later, on November 21, 2014, during a phone call, McFadden reprimanded Manieri for his comment to the RBM and criticized his management skills—something McFadden had never done before. (FAC ¶ 150; Compl. ¶ 133.) Manieri further alleged that McFadden told him he had “enough here to terminate you, but I’ll give you an opportunity to resign.” (FAC ¶ 151; Compl.

¶ 134.) “Mr. McFadden did not cite any reasons for the termination other than the suggestion [p]laintiff Manieri made to his direct report at the November 17 meeting.” (*Id.*) Manieri then alleged: “*As the result of this conversation*, Avanir terminated [p]laintiff Manieri’s employment on November 21, 2014.” (FAC ¶ 152 (emphasis added).) Notably, the phrase in italics was not included in the initial complaint, but was added to the FAC filed on December 17, 2019. (*See* Compl. ¶ 135.)

Manieri then alleged, in count one, that McFadden’s criticism of his management practices during the November 21, 2014 conversation was “pretext for retaliation for [his] opposition to Avanir’s illegal kickback scheme[,]” and that “Avanir terminated [his] employment in retaliation for his opposition to Avanir’s kickback scheme, in violation of 31 U.S.C. § 3730(h).” (FAC ¶¶ 165–66.) The corresponding allegations were in count four of the initial complaint. (*See* Compl. ¶¶ 158–59.)

Avanir filed a motion to dismiss the FAC, arguing that Manieri failed to sufficiently allege a claim for retaliation, having provided only “isolated and innocuous statements [that] do not come anywhere close to showing that [p]laintiff engaged in conduct protected by the FCA.” (Doc. No. 45, Motion to Dismiss [“MTD”], at 224 (citing FAC ¶¶ 93, 99).) Avanir also argued that Manieri failed to allege that Avanir knew he had engaged in protected conduct and, further, that plaintiff’s own complaint concedes the existence of a legitimate basis for his termination. (*Id.* at 225.)

On the day his response to the motion to dismiss was due, Manieri filed a motion for leave to file a second amended complaint to set forth more (and, as it turns out, different and sometimes inconsistent) factual detail around his alleged protected conduct and termination. He also sought (and was granted) an unopposed stay of the briefing on Avanir’s motion to dismiss pending

resolution of the motion for leave to file a second amended complaint. (See Doc. No. 47; Non-Document Order (3/19/2020).)

On July 28, 2020, the Court granted Manieri leave to amend his complaint a second time, concluding as follows:

Because of the liberal pleading standard articulated by Fed. R. Civ. P. 15(a), despite the unfortunate age of this case, and even though the proposed second amended complaint contains allegations that seem inconsistent with those in the first amended complaint, the Court grants plaintiff Manieri's motion for leave to file a second amended complaint. (Doc. No. 46.) Consequently, Avanir's motion to dismiss (Doc. No. 45) is rendered moot and shall be termed by the clerk.

The Court also concludes, under *Pennsylvania R. Co. [v. City of Girard*, 210 F.2d 437 (6th Cir. 1954)], and its progeny, that allegations in the original complaint and in the first amended complaint that are removed from the second amended complaint constitute admissions against interest that may be refuted by competent evidence at the appropriate time.

(MOO at 287–88.)

Manieri timely filed his Second Amended Complaint on July 29, 2020. (Doc. No. 51 (“SAC”).) Avanir timely filed the instant motion to dismiss, which is fully briefed and ripe for determination.

II. Discussion

A. Legal Standard

A complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief[.]” Fed. R. Civ. P. 8(a)(2). Although this pleading standard does not require great detail, the factual allegations in the complaint “must be enough to raise a right to relief above the speculative level.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (citing authorities). In other words, “Rule 8(a)(2) still requires a ‘showing,’ rather than a blanket assertion, of entitlement to relief.” *Id.* at 555, n.3 (criticizing the *Twombly* dissent’s

assertion that the pleading standard of Rule 8 “does not require, or even invite, the pleading of facts” (internal citation omitted).

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (quoting *Twombly*, 550 U.S. at 570). “While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.” *Id.* at 679. “The court need not, however, accept unwarranted factual inferences.” *Total Benefits Planning Agency, Inc. v. Anthem Blue Cross & Blue Shield*, 552 F.3d 430, 434 (6th Cir. 2008) (citing *Morgan v. Church’s Fried Chicken*, 829 F.2d 10, 12 (6th Cir. 1987)). “A complaint does not suffice if it tenders naked assertions devoid of further factual enhancement.” *Brown v. Matauszak*, 415 F. App’x 608, 613 (6th Cir. 2011) (internal quotation marks and citations omitted).

Additionally, the complaint must contain “either direct or inferential allegations respecting all material elements necessary for recovery under a viable legal theory.” *D’Ambrosio v. Marino*, 747 F.3d 378, 383 (6th Cir. 2014) (citations omitted). The fact of a previous settlement of claims between a defendant and the government has no bearing on whether the complaint adequately alleges plaintiff’s claims against the defendant. *See, e.g., U.S. ex rel. Scott v. Metro. Health Corp.*, 375 F. Supp. 2d 626 (W.D. Mich. 2005) (granting summary judgment for defendant in § 3730(h) retaliation case where defendant had previously settled with government resolving FCA allegations), *aff’d* 234 F. App’x 341 (6th Cir. 2007), *cert. denied*, 552 U.S. 1224, 128 S. Ct. 1225, 170 L. Ed. 2d 139 (2008).

B. Analysis

Under the FCA, “[i]n order to establish a claim for retaliatory discharge, a plaintiff must show: (1) he engaged in a protected activity; (2) his employer knew that he engaged in the protected activity; and (3) his employer discharged or otherwise discriminated against the employee as a result of the protected activity.” *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003) (citation omitted). Dismissal of a plaintiff’s claim is warranted where the plaintiff fails to establish any one of these elements. *Id.* Avanir argues that Manieri has failed to establish any of these elements.

1. Engaging in a Protected Activity under the FCA

“Protected activity” under the FCA refers to one of two types of action: (1) those “in furtherance of an action under [section 3730 of the FCA],” or (2) those “in furtherance of . . . other efforts to stop [one] or more violations of [the FCA].” *Kem v. Bering Straits Info. Tech.*, No. 2:14-cv-263, 2014 WL 5448402, at *2 (S.D. Ohio Oct. 22, 2014).

To demonstrate the first type of action, Manieri would need to allege that he had been pursuing a private qui tam action or assisting in such an action brought by the government and that Avanir had been placed on notice of that fact. Although Manieri did eventually file this qui tam action, there are no allegations in the complaint that he engaged in any such activities during the three to four months that he was employed by Avanir and/or that Avanir had been placed on any such notice.

As for the second type of protected activity, Manieri alleges two actions that he claims fall within this category—that he (1) “attempted to stop a violation of the FCA by refusing to allocate more money . . . to provide a kickback to Dr. [Raheja],” and (2) “engaged in protected activity under the FCA when he reported and objected to Avanir’s illegal kickback scheme to McFadden.”

(SAC ¶¶ 38, 39.) But, rather than plausibly alleging that he ever “attempted to stop” a violation of FCA, instead Manieri alleges that, although he believed unlawful kickbacks were being paid, he either failed to intervene or explicitly directed that they continue. In particular, Manieri alleges:

22. On or about September 29, 2019 [sic],³ regional business director Frank Mazzucco told Manieri that Avanir paid Dr. Raheja speaking fees to induce him to prescribe Nuedexta. Mazzucco further told Manieri that he needed additional speaker funds because he “need[ed] to have eight or nine speaking engagements guaranteed for Dr. Raheja.” When Manieri asked Mazzucco why the speaker funds that had already been allocated to his region were not enough, Mazzucco replied, “He’s our biggest prescriber and he likes to speak,” referring to Dr. Raheja. Manieri responded that he was concerned that Mazzucco was offering Dr. Raheja speaking engagements to encourage Dr. Raheja to prescribe Nuedexta. Mazzucco replied, “Well yeah, that’s kind of what I’m doing.”

23. Manieri told Mazzucco that he was not comfortable with his request for more speaker funds for Dr. Raheja and that Mazzucco should move forward with the existing funds that had been budgeted. Manieri also said he would reconsider the request if Mazzucco presented a compelling business reason why Avanir should budget additional funds for speaking programs.

(SAC ¶¶ 22–23 (clarifying footnote added).) Thus, when told about speaker payments that he believed to be unlawful, with an accompanying request to increase the amount budgeted for that purpose, rather than launch an investigation into the payments already budgeted, Manieri admits that he told Mazzucco to “move forward with the existing funds that had been budgeted[,]” and that he would “reconsider” should he be shown a “compelling business reason[.]” There is no allegation that Manieri reported any concerns to Avanir’s compliance program or legal department, initiated any disciplinary or corrective actions against Mazzucco, or took any other actions to stop the ongoing speaker payments. Manieri’s alleged provisional refusal to increase the budget for speaker fees, without more, does not rise to the level of an allegation of a “protected activity.”

³ From the context of other allegations in the complaint, it is clear that this date should be 2014.

Plaintiff’s second claim of protected activity—that he reported Avanir’s illegal kickback scheme to McFadden during an October telephone call—also fails. Manieri’s allegations confirm that he raised his purported concerns, not urgently, but only during “a regularly scheduled status call[]” on October 10, 2014—ten (10) days after his discussion with Mazzucco—and then only after McFadden affirmatively “asked Manieri about the speaker program budget allocation.” (SAC ¶¶ 28, 29.) Manieri claims that, as required “[p]er McFadden’s standing request, prior to the call Manieri sent McFadden an agenda of about five items to discuss during the call[]” (*id.* ¶ 28), but he does not allege that those agenda items included his alleged concern about speaker fees. The Court need not fill in that noticeable “blank” in the allegations by inferring an unpledged fact that is germane to Manieri’s retaliation claim. Moreover, Manieri does not claim to have told McFadden that he believed Avanir was engaging in illegal activity by way of the speaker payment program; Manieri merely stated that he was “concerned” about both the speaker funds and about Avanir’s relationship with Dr. Raheja, and that he felt Avanir was “crossing the line.” (*Id.* ¶¶ 29, 30.)

Manieri’s allegations fail because “to constitute protected activity, [an internal report] must specifically allege fraud on the government, and not just general misconduct.” *Miller v. Abbott Labs.*, No. 3:14-cv-363, 2015 WL 3773114, at *6 (W.D. Ky. June 17, 2015) (“[Section] 3730(h) requires more than merely reporting wrongdoing to supervisors[.]”); *see also McKenzie v. BellSouth Telecomm., Inc.*, 219 F.3d 508, 516 (6th Cir. 2000) (finding that the “in furtherance language” of the statute requires more than merely urging compliance with regulations).

The Sixth Circuit’s decision in *Fakorede v. Mid-South Heart Ctr., P.C.*, 709 F. App’x 787 (2017), an anti-retaliation claim brought under § 3730(h), is instructive. Like Manieri, the plaintiff in *Fakorede* claimed that he had “expressed concerns” about how expenses had been calculated

for him on an expense reimbursement report, “requested an independent review of the report” and “reminded others that an audit should check for compliance with federal law.” *Id.* at 789–90. The Sixth Circuit upheld dismissal of the complaint, explaining that one could not “reasonably infer from Fakorede’s complaint that his efforts were directed toward preventing what he reasonably believed was ongoing federal fraud.” *Id.* at 790.

As in *Fakorede*, this Court cannot assume that Manieri’s conduct “was directed at preventing possibly ‘tainted’ claims from being submitted to the *federal* government when nothing in the pleadings shows he understood, was motivated by, or even aware of that possibility.” *Id.* (emphasis in original) (citing *Iqbal*, 556 U.S. at 679).

Failure to establish that he was engaged in protected activity, by itself, is fatal to Manieri’s claim.

2. Employer’s Knowledge of Plaintiff’s Alleged Protected Activity

Even if Manieri had sufficiently alleged that he engaged in a “protected activity” within the meaning of the statute—which he has not done—he has also failed to plausibly allege that Avanir was on notice that he was engaged in such protected conduct. Notably, Manieri does not allege that he affirmatively reported alleged fraud on the government in the form of illegal speaker fees, asking his superiors to halt the activity. Manieri alleges only that McFadden, who “asked Manieri about the speaker program budget allocation[,]” (SAC ¶ 29), “knew or should have known” that the “concerns” Manieri expressed related to a purported kickback scheme. (*Id.* ¶ 32.)

This is insufficient to meet the notice standard. *See U.S. ex rel. Marlar v. BWXT Y-12, L.L.C.*, 525 F.3d 439, 445 (6th Cir. 2008) (“The elements of an FCA action must be pleaded with the particularity required by Rule 9(b).”) (citing *Yuhasz*, 341 F.3d at 563). These threadbare allegations do not satisfy the “burden of pleading facts which would demonstrate that defendants

had been put on notice” that Manieri was (or might be) engaged in protected activity as defined by the statute. *See Kaminski v. Teledyne Indus., Inc.*, 121 F.3d 708, 1997 WL 415314, at *6 (6th Cir. 1997) (table) (affirming Rule 12 dismissal where “amended complaint failed to plead facts demonstrating that, prior to her discharge, [plaintiff] was either taking action in furtherance of a private qui tam action or assisting in an FCA action brought by the government” but only alleged that she had “refused to approve the [allegedly fraudulent] mutual cessation agreement during the time she was employed”).

Manieri fails to establish this second element of a *prima facie* case of FCA retaliation.

3. Protected Activity as the “But For” Cause of Plaintiff’s Termination

To establish the third element of an FCA retaliation claim, plaintiff must demonstrate that he was terminated “because of” protected activity. 31 U.S.C. § 3730(h)(1). This “because of” language requires the employee to show “a causal connection between the protected activity and the adverse action.” *Scott v. Metro. Health Corp.*, 234 F. App’x at 346; *see also Gross v. FBL Fin. Servs., Inc.*, 557 U.S. 167, 176, 129 S. Ct. 2343, 174 L. Ed. 2d 119 (2009) (holding that the ordinary meaning of “because of” in the Age Discrimination in Employment Act required a plaintiff to prove that age was the “but-for” cause of the employer’s adverse action); *Univ. of Texas Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 362, 133 S. Ct. 2517, 186 L. Ed. 2d 503 (2013) (“[A] plaintiff making a retaliation claim under [Title VII] must establish that his or her protected activity was a but-for cause of the alleged adverse action by the employer.”).

Even if plaintiff had demonstrated both protected activity and Avanir’s notice of such activity, his claim would fail because he does not allege that his “protected activity” was the “but for” cause of his termination. In both his original complaint and his first amended complaint, Manieri alleged that his termination resulted from a conversation he had with McFadden in

November of 2014, wherein McFadden reported that a complaint had been lodged against Manieri by another regional manager regarding Manieri's management skills. Manieri alleged that McFadden told him he had "enough here to terminate [him], but . . . [would] give [him] an opportunity to resign." (Compl. ¶ 134; FAC ¶ 151.) When those pleadings were challenged by Avanir, Manieri sought and was granted leave to file his second amended complaint, wherein he eliminates those allegations and changes his story, asserting that the termination resulted from a conversation with McFadden at a regular conference in October 2014 wherein Manieri claims to have raised concerns with McFadden about payments to physicians. After speculating that McFadden "knew or should have known" that Manieri's "concerns" related to a "kickback scheme" (SAC ¶ 32), Manieri then simply states that his employment was terminated in November 2014, a "little over a month after [he] reported his concerns" to McFadden, with "no reason [given] for the termination." (*Id.* ¶ 34.) The speculative inference is that he must have been terminated for raising his concerns in October 2014. These allegations are insufficient to establish the requisite "but for" causation—even if there were actual protected activity and notice to Avanir.

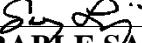
Plaintiff fails to establish the third element of a *prima facie* case of FCA retaliation.

III. Conclusion

For the reasons set forth herein, Avanir Pharmaceuticals, Inc.'s motion to dismiss plaintiff Kevin Manieri's second amended complaint for failure to state a claim (Doc. No. 52) is granted.

IT IS SO ORDERED.

Dated: March 8, 2021


HONORABLE SARA LIOI
UNITED STATES DISTRICT JUDGE